The New Orleans Hernia Event Reduction, a Novel Indication for Amnion (NO HERNIA) Trial

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Introduction

- Incisional hernias (IH) are one of the most common postoperative compilations following open abdominal surgery.[1]
- IH repairs fail in up to 60% of cases.[2]
- No standard of care for IH prophylaxis exists.
- In a previous xenograft animal model and subsequent prospective study of patients that are at high-risk of developing IH, placement of a dehydrated human amniotic-chorionic membrane (dHACM) significantly reduced IH formation by 64% and 88%, respectively.

Objective: **Evaluate the effects of a standard abdominal fascial closure combined with placement of dHACM in reducing IH incidence within high-risk populations.**

Methods

- Prospective, Double-Blinded, Multi-Centered Randomized Controlled Trial: Treatment (dHACM) versus control (standard closure) (NCT04417140).
- Inclusion: Patients with a >150% risk of developing an IH following abdominal surgeries with incisions >6 cm.[2]
- Target Enrollment: 533 subjects (interims: 142 and 284 patients). We have been recruiting patients since 2020.
- Evaluation: At 6 months post-operation, subjects are evaluated by a blinded evaluator via ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan to determine the presence of an IH, along with the length of the incision and a subjective pain score.

Procedure and Analysis

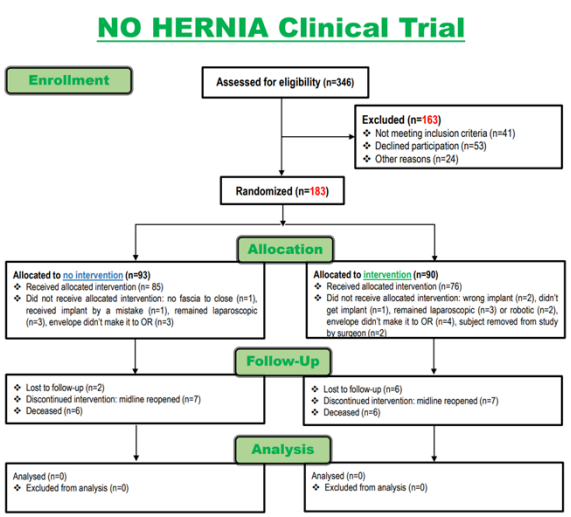

Figure 1. Consort flow diagram of the NO Hernia Trial as of September 2022.

Primary Analysis

- The rate of IH formation defined as midline fascial defect and hernia sac >4 mm in diameter in dHACM-treated versus control subjects.

Secondary Analysis

- The rate of postoperative complications in dHACM-treated versus control subjects:
  - Hematoma
  - Intestinal paralysis
  - 30-day in-hospital mortality
  - Fistula formation
  - Small-bowel obstruction
  - Surgical site infection (SSI)

Summary

- 346 patients screened, 183 enrolled.

Future Directions/Conclusions

- Additional patient enrollment and subsequent 6-month post-operative assessments are necessary to determine the effectiveness of dHACM in reducing IH formation following open abdominal surgery.
- Interim analysis will be performed after successful follow-ups of patients #142 and #284.

References

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